



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

May 11, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vincent S. Kandis
CEO
Euthenics International, Inc.
400 Corporate Circle, Unit L
Golden, Colorado 80401

Ref #: DEN-00-19

Dear Mr. Kandis:

This letter is in reference to your firm's marketing and distribution of the products, Testasomal 200 and Decasomal 200. Labeling for these products contains therapeutic claims, which cause the products to be drugs [Section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)].

Labeling is not limited to the immediate product containers but includes all promotional literature, which you distribute that accompanies your products.

Objectionable claims for Testasomal 200 and Decasomal 200 include the following:

Any use of the terms “transdermal” or “lipsomal”

“delivers prohormone compounds into the body far more effectively than the delivery system used for powerful prescription anabolic steroids”

“lost body fat and gained muscle like I never thought possible”

“delivers massive surges of the most potent prohormones”

“1) More strength! 2) More size! 3) More hardness! 4) Fuller nitrogen saturated muscles!
5) Bigger monster pumps 6) More endurance! 7) Faster recovery”

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“Get your levels high...then keep them high all day, all week, all month”

“You must have consistent and high testosterone production – all the time...This new supercharged delivery system...will do just that”

In addition, these products are transdermal because they are intended to deliver active ingredients “directly through your skin into your bloodstream,” and are intended to have a systemic effect on the body. In 1989, the Agency made a determination that transdermal delivery systems are new drugs based on the newness of the delivery system [Title 21, Code of Federal Regulations (21 CFR), Section 310.3].

Testasomal 200 and Decasomal 200 are “new drugs” [Section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [Section 505(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

Further, claims for additional products are included on your firm’s Internet web site. Such claims may also cause these products to be misbranded. Products and claims include:

- | | |
|----------|--|
| 5-H.T.P. | Comparison to the prescription drug Prozac, depression, insomnia, anxiety, headaches. |
| Chitosan | Inhibit bad cholesterol and boost good cholesterol, acts as an antacid and may be beneficial in healing ulcers and lesions, irritable bowel syndrome, antibacterial. |

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

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Your reply should be directed to the Food and Drug Administration, Attention: Ms. Jeannette A Schmieg, Acting Compliance Officer, at the above address.

Sincerely,

A handwritten signature in cursive script, reading "Karen S. Kreuzer". The signature is fluid and elegant, with a long horizontal flourish extending to the right.

Karen S. Kreuzer
Acting District Director

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